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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,676	01/26/2004	Peter Rohnert	13183.0037	9441
<div>26712      7590      12/31/2007</div> <div>HODGSON RUSS LLP THE GUARANTY BUILDING 140 PEARL STREET SUITE 100 BUFFALO, NY 14202-4040</div>				
			EXAMINER SOLOLA, TAOFIQ A	
			ART UNIT 1625	PAPER NUMBER
			MAIL DATE 12/31/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/764,676

Applicant(s)

ROHNERT ET AL.

Examiner

Taofiq A. Solola

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 05 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 45-63 and 82-86 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 45-63, 82-86 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Claims 45-63, 82-86 are pending in this application.

Claims 1-44, 64-81 are cancelled.

### ***Request for Continued Examination***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.117(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/5/07 has been entered.

### ***Status of Claims***

In Paper filed 12/14/06, claims 45-86 are pending. In the paper filed 8/9/07, claims 45-63, 82-83 are listed as pending, and claims 64-81 canceled. Claims 84-86 are not listed and their status not indicated on the list of claims. The document should have been returned to applicant as improper listing of claims by the Legal Instrument Examiner. The short listing is missed by the Examiner also.

The rejection of claims 45-63, 82-86, under 35 USC 103(a) as well as the objection to the abstract and figures set forth in the last Office action is hereby maintained.

### ***Response to Argument***

Applicant's arguments filed 11/5/07 have been fully considered but they are not persuasive. Applicant contends there is no evidence on record that one of ordinary skill in the art would have expected synergistic effect from the instant invention at the time it was made. This is not persuasive because the contention ignores historical evidence of knowledge in the art of practicing combinatorial therapy in medicine. Applicant also

argues that ambroxol has no neuroprotective effect. This contradicts the result in the specification (Table 2b), wherein ambroxol alone show a difference of 2.58 while the cocktail shows 3.46, about 75 percent.

Ambroxol, alpha lipoic acid and ACE inhibitors are not applicant's invention. They are in public domain before the time the instant invention was made. Applicant has done no more than combine separate but well-known inventions. While the combination may perform a useful function (neuroprotection) it did no more than what they would have done separately (mode of action). *In re Anderson*, 396 U.S. 57, 163 USPQ 673 (1969) cited in *KSR Int. Co. v. Teleflex Inc.*, 550 U.S. ----, 82 USPQ2d 1385 (2007). When a patent simply arranges old elements with each performing the same function it had been known to perform and yields predictable result, the combination is obvious. *In re Sakraida*, 425 US 273, 189 USPQ 449 (1976) cited in *KSR, supra*. A patent for such combination "obviously withdraws what is already known into the field of its monopoly." *Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147, 187 USPQ 303 (1950), cited in *KSR, supra*.

This is RCE of the same Application. All claims are drawn to the same invention claimed earlier in the application and have been finally rejected on the same grounds. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

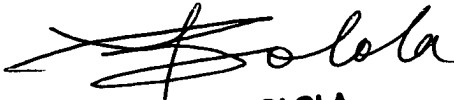
shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD. JD., whose telephone number is (571) 272-0709.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

  
**TAOFIQ SOLOLA**  
**PRIMARY EXAMINER**  
Group 1625

December 24, 2007